

**REMARKS**

Claims 22-58 presently appear in this case. No claims have been allowed. The official action of April 4, 2007, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating a viral infection by the administration of interferon via oromucosal contact. The dose is a high dose which is greater than about  $0.28 \times 10^6$  IU of interferon per kg body weight of the patient, preferably greater than  $30 \times 10^6$  IU of interferon, which dose is in excess of a dose of the same interferon which induces a pathological response when parenterally administered.

Claims 36 has been rejected because of the misspelling of the word "oromucosal".

This misspelling has now been corrected, thus obviating this rejection.

Claims 36 and 38-51 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The examiner states that this is a new matter rejection. The examiner states that the recitation "... and provided that when the viral infection is a rhinoviral infection, the interferon is not administered through the mouth in a multiple or continuous dose" is new

matter. The examiner concedes that there is support for the individual teachings of rhinovirous, nasal administration, administration by multiple or continuous doses and administration in a single dose which is not a multiple or continuous dose. However, the examiner states that there is no specific contemplation of combinations of these teachings.

Claim 36 has now been amended to delete the phrase that the examiner considers to be new matter and instead to specify that the interferon is administered intranasally. The examiner has conceded that this teaching appears in the specification. Furthermore, this statement in the claim is sufficient to define over Eby, as Eby tells one not to administer intranasally. Furthermore, new claim 58 has now been added which is the same as previously appearing claim 36 but instead of the objected to phrase at the end, specifies that the interferon is administered in a single unit dose, with language which is the same as appears in claim 38. Claim 58 also defines over Eby, as Eby teaches that one should not administer in a single unit dose. With these amendments, it is urged that the new matter rejection is now been obviated. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

Claims 22-57 have been rejected under 35 U.S.C. 112, first paragraph, because the specification, while being

enabling for biologically active interferon not entering the bloodstream, does not reasonably provide enablement for interferon not entering the bloodstream. The examiner states that amending the claims to recite that "biologically active interferon" does not enter the bloodstream would overcome this rejection.

Claims 36, 37 and 52 have now been amended to recite that "biologically active interferon" does not enter the bloodstream, thus obviating this rejection.

Claims 22-57 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the use of the term "for a 70 kg human." The examiner states that this dose limitation only applies to a 70 kg human and thus it is not clear at what dose the interferon would be administered to humans not weighing 70 kg.

While applicants disagree with this interpretation, claims 36 and 52 have now been amended to use the language found in the present specification at page 8 that the dosage is greater than  $0.28 \times 10^6$  IU of interferon per kg body weight of the patient. This applies to patients of any weight and thus obviates this rejection. Claim 37 has been amended to delete reference to a 70 kg human and instead to simply specify that in all patients the amount that is administered is greater than  $30 \times 10^6$  IU. Thus this rejection has also been

obviated for claim 37. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

The examiner states that claims 22 and 23 recite the limitation "the effective amount" in line 2 but there is insufficient antecedent basis for this limitation. The examiner points out that claim 37, from which these claims depend, does not recite "effective" amount.

Claims 22 and 23 have now been amended to delete the term "effective amount" and instead use "the amount of greater than  $30 \times 10^6$  IU interferon," which is supported in claim 37. Although, claim 24 was not included in this rejection, a similar amendment was made to claim 24. Accordingly, reconsideration and withdrawal of this part of the rejection is also respectfully urged.

Claims 22-35 and 37 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Eby. The examiner states that these claims recite methods for treating viral infections comprising administering greater than  $30 \times 10^6$  of an interferon for a 70 kg human by oromucosal contact. The examiner interprets this language as meaning that the claims read on any dose being administered to humans not weighing 70 kg. The examiner considers this to read on the administration of Eby. This rejection is respectfully traversed.

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Claim 37 has now been amended to clarify that the minimum dose is  $30 \times 10^6$  IU regardless of the size of the patient. This is 50% more than the maximum dose disclosed by Eby. Accordingly, now that the claims have been clarified, it should be clear that such a large difference in dosages would not have been obvious to any one skilled in the art reading Eby. Reconsideration and withdrawal of this rejection is therefore respectfully urged.

All of the claims now present in the case clearly define over the references of record and fully comply with 35 U.S.C. 112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant(s)

By /rlb/  
Roger L. Browdy  
Registration No. 25,618

RLB:srd  
Telephone No.: (202) 628-5197  
Facsimile No.: (202) 737-3528  
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